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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,114	11/14/2005	F. C. Allnutt	026086.037.21 US	9387
24239 7590 02/01/2010 MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709				
EXAMINER				
BLUMEL, BENJAMIN P				
ART UNIT		PAPER NUMBER		
1648				
MAIL DATE		DELIVERY MODE		
02/01/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/519,114

## Applicant(s)

ALLNUTT ET AL.

## Examiner

BENJAMIN P. BLUMEL

## Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12/20/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 27,30-32,34,35,37 and 42-47 is/are pending in the application.
- 4a) Of the above claim(s) 42-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27,30-32,34,35 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/23/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/20/09 has been entered.

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

Claims 42-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/19/07.

Claims 27, 30-32, 34, 35 and 37 are examined on the merits.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless

the references have been cited by the examiner on form PTO-892, they have not been considered.

***Response to Arguments***

Applicant's arguments with respect to claims 27, 30-32, 34, 35 and 37 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**(New Rejections)**

Claims 27, 30-32, 34, 35 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 recites the limitation "in the host organism" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claims 30-32 are rejected since they depend from claim 27.

Claim 27 recites, "...a first and second exogenous protein for expression in the host organism and the exogenous proteins target specific tissue in a target animal...", however, claim 27 also recites, "... (c) ...first exogenous sequence encoding a protein or peptide...is antigenic or allergenic in the target animal..." Therefore, it is unclear if the first exogenous sequence encodes an antigenic or allergenic protein or one that targets specific tissues in the target animal.

Claim 27 recites, "...inserting at least one second exogenous sequence encoding a tissue-targeting protein sequence in the animal into the coat protein sequences...", however, it is

unclear if the sequence encoding a tissue-targeting sequence is inserted into the animal or the coat protein (see underlines).

Claims 27 and 34 recite, "...the host organism and the target animal are not the same.", however, it is unclear if this implies that if the host organism is a fish, then the target animal is not a fish or can it be a different species of fish in comparison to the host organism?

Claim 31 recites, "...wherein...the second exogenous sequences has the function of targeting the expressed recombinant virus-like particle to a specific location.", however, it is unclear where this "specific location" may be. Is it a tissue, host cell, agglomeration complex in the circulatory system or G.I. tract, or some other location within the target animal or host organism? Claim 34 is also rejected under the same rationale since it too recites, "...a specific location on tissue in the target animal...".

Claim 32 recites the limitation "viral coat protein is isolated" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is suggested that claim 32 alternatively recite, "...more than one viral coat protein sequence is isolated."

Claim 34 is drawn to a genetic construct that encodes at least one viral coat protein and two exogenous sequences that encode for an antigen or allergen and a tissue-targeting protein. These exogenous sequences are positioned on the expressed viral coat protein. However, claim 34 also recites multiple active steps of using this construct in the expression of proteins in a host organism and the administration of the construct expressing host organism to a target animal which is different from the host organism. Therefore, it is unclear if the claimed invention is in fact drawn to a genetic construct that encodes for a viral coat protein and two exogenous proteins or a method of making these proteins or a method of administering the combination of the host

organism (i.e., yeast, bacteria, algae, fish or crustacean) which also contains the expressed proteins of the construct to a target animal. Claims 35 and 37 are also rejected since the depend

Claim 34 recites, "...wherein both the antigenic or allergenic protein and tissue-targeting protein, when expressed in the host organism, are positioned on the expressed viral coat protein..." However, it is unclear what the metes and bounds of "positioned" are? Does this mean fused, associated, linked, etc.

Claim 35 recites, "...more than one viral coat protein has been modified to display foreign proteins or peptides.", however, it is unclear what the metes and bounds of "modified" are. In order to "display" the foreign components, has the viral coat protein been fused to these foreign proteins/peptides; chemically linked; associated through non-covalent means; or some other biochemical process. It is further unclear since claim 34 only recites, that the exogenous proteins be "positioned" on the viral coat protein.

Claim 35 recites the limitation "foreign proteins or peptides" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 37 recites, "...wherein the exogenous sequence is inserted into a region truncated to remove sequence unnecessary for virus-like particle self-assembly." However, it is unclear if both exogenous sequences are inserted into this region or if the first or second exogenous sequences are inserted. Furthermore, it is unclear if the exogenous sequences are to be positioned with the viral coat protein (see claim 34), which is involved in self-assembly, how can the exogenous sequence be inserted into any region that does not affect self-assembly and still be expected to be positioned with the coat protein. In addition, since claim 34 only recites that the viral coat protein encoding sequence be present and does not recite any language relating to viral

genomes, how can the exogenous sequence be inserted into a region, when the region or something that would contain the region (i.e., genome or gene or locus) is not claimed.

***Claim Rejections - 35 USC § 102***

**(New Rejection)** Claims 27, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Bachmann et al. (US PGPub 2003/0099668 A1).

The claimed invention is drawn to a method of producing a recombinant virus-like particle (VLP) from a recombinant expression construct. The recombinant VLP contains at least one capsid/coat protein and at least one exogenous sequence that encodes an antigen or allergen specific for a target animal and at least one exogenous sequence that encodes a tissue-targeting protein that has an affinity for a receptor on tissue in the target animal. These exogenous sequences are inserted into the coat protein sequence(s) and these sequences are inserted into a vector that is transformed into a host organism (such as fish, crustacean, bacteria, yeast or algae). The viral genome that provides the coat/capsid protein gene sequence can infect the host organism and the host organism is different from the target animal. The claimed invention also includes that more than one first exogenous sequence is inserted.

Bachmann et al. teach the expression of recombinant VLPs and recombinant virus coat proteins that also contain heterologous protein sequences expressed with the coat proteins. Bachmann et al. utilize VLPs and coat proteins from bacteriophages (viruses that infect bacteria-one of the claimed hosts) and viruses important to the animal kingdom. Bachmann et al. teach the insertion of genes coding for the antigens or allergens of interest and the use of genes that code for lipopeptides that interact with Toll-Like Receptors in mammalian hosts. More specifically, Bachmann et al. teach the insertion of antigens into the coat protein of RNA

bacteriophage Q-beta in order to present these antigens on the surface of the phage. Bachmann et al. also teach the use of yeast cells to express recombinant VLPs. Therefore, Bachmann et al. anticipate the claimed invention. *See paragraphs 27-33, 131, 231, 241-260 and Example 6.*

**(New Rejection Necessitated by Amendments)** Claim 34 is rejected under 35 U.S.C. 102(c) as being anticipated by Bachmann et al. (*Supra*).

The claimed invention is drawn to a genetic construct that encodes at least one viral coat protein and at least one first exogenous sequence that encodes for an antigenic or allergenic in the target animal and at least one second exogenous sequence that encodes for a tissue-targeting protein of a tissue in an animal. These exogenous sequences are positioned on the coat protein and the tissue-targeting protein targets the first exogenous protein in the target animal. The construct can be expressed in a host organism selected from yeast, bacteria, algae, fish or a crustacean. In addition, the target animal is different from the host organism.

The claimed product also requires that it is for expressing the above proteins in the host organism and can be administered with the host organism to the target animal.

However, the MPEP § 2111.02 (II) recites, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Therefore, for purposes of examination, the intended uses of the expressed construct/host organism are not interpreted to further limit the claimed



invention. Therefore, the specific sequences inserted into the construct and the ability of the construct to be expressed in the claimed host organism will be examined.

The teachings of Bachmann et al. are discussed above, therefore, the claimed invention is anticipated.

### ***Claim Objections***

**(New Objection Necessitated by Amendments)** Claim 27 is objected to because of the following informalities: step (e), the claim recites, "...into an appropriate vector for infection of the host organism...", however, since the vector is intended for transformation or transfection protocols, but not actual infection of a host, it is suggested that the claim be amended to reflect this functional limitation. Such as, "...into an appropriate vector for transformation of the host organism..."

**(New Objection)** Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 31 recites, "...second exogenous sequences has the function of targeting the expressed recombinant virus-like particle to a specific location.", however, claim 27 requires that the second exogenous targets a specific tissue in the target animal. This requirement in claim 27 is narrower in scope than the recitation of "a specific location" in claim 31.

**(New Objection)** Claim 34 is objected to because of the following informalities: in line 8, antigenic and allergenic are misspelled. Appropriate correction is required.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/  
Examiner  
Art Unit 1648